

"A Support Element for an Integrated Module for Blood Treatment, an Integrated Module for Blood Treatment, and a Manufacturing Process for an Integrated Module for Blood Treatment."

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5 BACKGROUND OF THE INVENTION

The invention relates to a support element, to an integrated module for blood treatment comprising the support element, and to an apparatus for extracorporeal treatment of blood equipped with the integrated module. The invention also relates to a manufacturing
10 process for an integrated module for blood treatment.

As is known, for carrying out extracorporeal blood treatments, such as, for example, hemodialysis, hemofiltration, hemodiafiltration, plasmapheresis, extracorporeal blood oxygenation, extracorporeal blood filtration or other treatments, there must be present at least
15 one extracorporeal circuit through which the blood is made to circulate in order to be transported towards a treatment device. The treated blood is then returned to the patient's cardiovascular system.

With reference, by way of example, to a dialysis treatment, the
20 extracorporeal circuit used comprises: a dialysis filter constituted by a container body including at least a first and a second chamber, separated from each other by a semipermeable membrane, a blood withdrawal line leading to the first chamber of the dialyzer filter and a blood return line destined to receive blood outletting from
25 the first chamber and to return it to the patient. The second chamber of the dialyzer filter is connected to a dialysis liquid circulation circuit destined to receive the impurities present in the blood, as well as the excess fluid which is to be removed from the patient's blood.

30 At present, in extracorporeal blood treatment apparatus, the totality of lines destined for dialysis liquid circulation is housed inside the dialysis machine, while the lines forming the

extracorporeal blood circuit are changed after each single treatment and are connected to the dialyzer filter, which can be changed either at each treatment or periodically, according to needs.

From the structural point of view, the dialyzer filter, the dialysis
 5 liquid circulation lines and the lines forming the patient's blood withdrawal and return branches are constituted by separate parts which are connected up and cooperate operatively following assembly.

The market offers apparatus, in particular destined for intensive kidney failure treatment, which are advantageously provided with
 10 integrated modules comprising a support structure, a dialyzer filter constrained to the support structure by means of a support element emerging from the support structure, as well as a hydraulic circuit comprising the tubing necessary for defining the withdrawal branch and the return branch of the blood from and to the patient, the
 15 lines (if present) for infusion of anticoagulant, or of substitution liquids, the dialysis liquid supply line, the discharge line for discharge liquid outletting from the dialysis filter second chamber.

The above-described integrated modules enable an easy and immediate attachment of the lines on the treatment apparatus and do not need
 20 any connection between the treatment device, for example a dialyzer filter, and the various tubes or lines destined to carry blood and other fluids. Further, the integrated modules enable removal both of the tubes carrying the blood and those carrying other fluids once the treatment has been concluded. In other words, with a simple
 25 loading operation and a connecting-up of the terminals and the fluid transport lines to the relative sources, i.e. bags or other, the user can start up the dialysis apparatus.

Similarly, once the treatment has been concluded, a small number of disconnecting operations and dismounting of the integrated module
 30 from the blood treatment machine will enable the operator to completely remove the extracorporeal circuit, the blood treatment device, any tubing for circulation of infusion liquids as well as for the dialysis liquid.

The ease with which the module can be set up guarantees efficiency and speed, much to be appreciated in the case of intensive treatment, where the personnel involved, not necessarily expert in the use of blood treatment machines, can operate quickly and
5 extremely reliably.

Though the above-described integrated modules have had a notable market success, they have shown themselves to be susceptible to improvement in various aspects.

Firstly, in the prior art, the connection between the support body
10 and the blood treatment device includes an additional support interpositioned between the body of the treatment device and the support element, considerably complicating the overall structure of the integrated model.

The presence of an intermediate support structure between the
15 support body and the dialyzer body causes the integrated module to be considerably unwieldy.

Additionally, the need to connect the dialyzer filter or another treatment device used with the extracorporeal blood circuit lines and the treatment fluid lines constitutes a further difficulty, as
20 the connecting-up operations have to be performed in a zone which is difficult to access.

The above has obviously hampered the possibility of automating the assembly stages, considerably increasing production costs of the integrated modules at present on the market.

25 SUMMARY OF THE INVENTION

A main aim of the present invention is to make available a support element for an integrated module for blood treatment, and an integrated module for blood treatment comprising the support element, which overcome all of the above-described limitations and
30 drawbacks.

In particular, an aim of the present invention is to provide a new support element which is easily and automatically assemblable with a

blood treatment device, consequently reducing the overall costs for realization of an integrated module for extracorporeal blood treatment.

5 These aims and more besides will better emerge from the detailed description that follows, of a support element and an integrated module for blood treatment, comprising the support element as characterized in one or more of the appended claims.

10 Further characteristics and advantages will better emerge from the detailed description that follows of some preferred embodiments of a support element and an integrated module incorporating the support element of the present invention.

The following detailed description will also illustrate a manufacturing process of an integrated module for blood treatment, according to the invention.

15 **BRIEF DESCRIPTION OF THE DRAWINGS**

The detailed description will now be made with reference to the accompanying figures of the drawings, provided as a non-limiting example, in which:

- Figure 1 is a perspective view of a support element for an
20 integrated module according to a first embodiment of the invention;
- Figure 2 shows the support element of figure 1 in an upturned position relative to the position of figure 1;
- Figure 3 is a perspective view of a cover for closing an open side of the support element of figure 1;
- 25 - Figure 4 is a perspective view of a support element for an integrated module in a second embodiment of the invention;
- Figure 5 shows the support element of figure 4 in an upturned position relative to the position of figure 4;
- Figure 6 is a perspective view of an integrated module for

extracorporeal treatment of blood with the support element of figure 5;

- Figure 7a shows a detail of the module of figure 6, relating to a coupling between a seating of the support element and a corresponding connector of a blood treatment device;

- Figure 7b shows a detail of figure 1;

- Figure 8 schematically illustrates the module of figure 6 constrained on a frontal operative wall of a machine for extracorporeal blood treatment;

10 - Figure 9 is a schematic representation of the module of figure 6 in CRRT (continuous renal replacement therapy) configuration.

DETAILED DESCRIPTION

With reference to the accompanying figures of the drawings, 1 denotes in its entirety an integrated module for blood treatment in accordance with the present invention. The module 1 can be engaged to a machine for extracorporeal blood treatment 2, provided with one or more pumps 3 destined to cooperate with the module 1. The module 1 comprises a support element 4 to which a blood treatment device 5, for example a plasma-filter, a hemodialysis filter, a hemofiltration filter, a filter for hemodiafiltration or a different unit.

In greater detail, the support element 4 comprises a base body 6 exhibiting at least a first and at least a second connector 7 and 8, distanced one from another, destined to receive and connect with corresponding counter-connectors 9 and 10 of the blood treatment device 5. The first and second connectors 7 and 8 are directly constrained to the base body 6; in the illustrated embodiments the connectors 7 and 8 are made of a rigid plastic material and in a single piece with the base body 6.

The support element 4 exhibits a third connector 11, distanced from the connectors 7, 8 and directly constrained on the base body 6; in the illustrated embodiments the third connector 11 is made of rigid

plastic material and in a single piece with the base body 6; the three connectors define pairs of connectors having differentiated interaxes for engaging with corresponding pairs of counter-connectors associated to different blood treatment devices which are mountable on the support element 4. This is so that a single base body 6 can be used to realize integrated modules having different characteristics, thanks to the possibility of engaging treatment devices 5 which are not only different as regards the membrane, but also in terms of overall size and therefore interaxes of the relative counter-connectors.

Each of the connectors 7, 8, 11 constitutes a rigid support and defines a fluid passage having a first end portion 12, destined to be placed in fluid communication with a corresponding channel 13 present in a respective counter-connector 9, 10 exhibited by the blood treatment device 5; each connector 7, 8, 11 also exhibits a second end portion 14, destined to be placed in fluid communication with a fluid distribution circuitry 15 associable to the base body 6. In a further structural detail, each of the connectors 7, 8, 11 comprises a tubular channel 16, defining the first end portion 12, a sealing collar 17, in a position which is radially external to the tubular channel 16, and a connecting wall 18, which develops continuously between an external lateral surface 19 of the tubular channel 16 and an internal lateral surface 20 of the sealing collar 17.

The external lateral surface 19 of the tubular channel 16, the internal lateral surface 20 of the sealing collar 17 and the connecting wall 18 together define an annular seating 21, a bottom of which is delimited by the connecting wall 18, shaped in order to receive and engage a corresponding counter-connector of the blood treatment device.

The tubular channel 16 is coaxially arranged with respect to the sealing collar 17, and has geometry of revolution there-with, with a common axis of symmetry. The annular seating 21 exhibits an increasing radial dimension as it progresses from the bottom connecting wall 18; it comprises a first zone 22, adjacent to the

bottom and having a constant radial dimension; a second zone 23, distal with respect to the bottom and having a constant radial dimension which is greater than the radial dimension of the first zone 22; and a third zone 24, which is a transit zone between the
5 first and second zones 22 and 23 and which has a progressively growing radial dimension as it progresses away from the bottom connecting wall 18.

The tubular channel 16 and the sealing collar 17 of each connector 7, 8, 11 are parallel to one another in the base body 6, defining a
10 single coupling direction with the corresponding counter-connectors of a treatment device 5.

In the illustrated embodiments, the various counter-connectors and connectors exhibit axes of symmetry which are perpendicular to a frontal wall 25 of the support element 4.

15 The support element 4 shown in figures 4-7 further comprises a fourth connector 26 which is distanced from the first, second and third connectors 7, 8 and 11. The fourth connector 26 is also directly connected to the support element 4.

In the embodiment of figures 4-7 the fourth connector 26 is made of
20 rigid plastic in a single piece with the base body 6 and defines, with at least one of the other connectors 7, 8 and 11 a further pair of connectors which can be engaged to a corresponding pair of counter-connectors associated to a blood treatment device mountable to the support element 4.

25 The fourth connector 26 comprises a central cylindrical body 27 for positioning, a sealing collar 28 located in a radially external position with respect to the central cylindrical body 27, and a bottom connecting wall 29 which develops continuously between an external lateral surface 30 of the central cylindrical body 27 and
30 an internal lateral surface 31 of the collar 28. The fourth connector 26 defines a connecting and sealing site for a counter-connector of the blood treatment device 5.

As shown in figures 6, 7a (and the same goes for the support

elements of figures 1-3, 7b), the various connectors are made of rigid material in order to offer a mechanical support to the blood treatment device and, according to each individual case, to define a passage or an obstruction for fluid passing through the counter-
5 connectors 9, 10.

In the support element of figures 4-6 the four connectors are aligned and arranged on one side of the base body 6. More precisely, the base body 6 of the element illustrated in figures 4-6 and 7a comprises a frontal wall 25 and a perimeter wall 32 connected around
10 an edge thereof to the frontal wall 25, which together define a works housing area 33 which can house at least a portion of the works of the support element, i.e. a fluid distribution circuitry 15 destined to be associated to the support element 4.

The works housing area 33 exhibits an open side 34 which enables the
15 integrated module 1 to be correctly positioned and adequately locked onto the machine, as will be better described herein below.

The support element 4 exhibits an auxiliary structure 35 which extends laterally and externally with respect to the works housing area 33 from a base zone 36 of the perimeter wall 32. The four
20 connectors emerge from the auxiliary structure 35: the first, second and fourth connector 7, 8, 26 are adjacently situated, and arranged at a first end zone 37 of the auxiliary structure 35, while the third connector 11 is located at a second end zone 38, opposite the first end zone 37.

25 In the illustrated embodiment of figures 1-3, the base body 6 comprises a frontal wall 25 and a perimeter wall 32 joined at an edge thereof to the frontal wall 25, defining a works housing area 33 which can house at least a portion of the fluid distribution circuitry 15 destined to be associated to the support element 4.

30 In this embodiment, however, the connectors 7, 8 and 11 are not aligned and emerge directly from the frontal wall 25. Further, a cover 39 is associated to the perimeter wall 32 on an opposite edge thereof with respect to the frontal wall 25.

A support element according to the invention can advantageously be used for realizing an integrated module, such as for example the module illustrated in figure 6, where by way of example the support element 4 of figures 4 and 5 is used.

5 As can be observed, the blood treatment device 5 is fixed to the support element 4 by at least one pair of connectors; the blood treatment device comprises a body 40, at least one semipermeable membrane 41 (for example a parallel hollow fiber membrane or a plate membrane) operating internally of the body 40 and defining a first
10 chamber and a second chamber; a first and a second connector are associated to the body 40 and fixed to the respective connectors on the base body 6.

The first and second counter-connectors 9, 10, are tubular and are in fluid communication with the second chamber of the treatment
15 device and with respective first end portions 12 of the connectors.

The treatment device exhibits an inlet port 42 to the first chamber, and at least one outlet port 43 from the first chamber, for connection of an extracorporeal blood circuit line 44 or another physiological fluid.

20 A fluid distribution circuitry 15 is attached to the support element 4 and cooperates with the treatment device 5. In more detail, the circuitry comprises:

- at least one discharge line 45 of discharge fluid, in communication with the second terminal portion 14 of one of the
25 connectors;

- at least one blood line 44 having a blood withdrawal branch 46, placed in communication with the inlet 42 of the first chamber, and at least one branch 47 of a blood return line, placed in communication with the outlet 43 of the first chamber;

- 30 - at least one supply line 48 of fresh dialysis liquid, placed in communication with the second end portion 14 of another of the connectors.

Each of the lines is constrained to the support element 4, defining at least one tract of tubing 49 which is arranged in a U-shape, in relation to the support element 4.

During operation the U-shaped tracts are destined to cooperate with the respective peristaltic pumps 3 located on a panel of a machine for extracorporeal blood treatment. Each tract of U-shaped tubing extends internally or externally (figure 7) with respect to the perimeter wall 32 of the support element 4.

Figure 9 is a diagram of the integrated module 1 in the CRRT configuration. As can be observed, the module 1 also has lines 50 and 51 for respective pre and post blood pump infusions (pre-dilution and/or post-dilution).

An air separator device 52 operates on the branch 47 of the blood line 44 and receives an infusion line 51.

The invention also relates to an assembly procedure for an integrated module for fluid treatment which comprises the stages of predisposing a support element 4, for example such as in figures 1-3 or in figures 4-6, as well as a treatment device 5 which is intended for coupling to the support element 4. The blood treatment device 5 is then fixed to the support element 4. Finally a fluid distribution circuitry 15 is associated to the support element 4 and to the blood treatment device 5 so as to create the necessary blood circulation lines, the discharge lines, the infusion lines for any liquid substitution lines, and dialysis lines.

The connection of the distribution circuitry to the blood treatment device can be done before, at the same time as or after the circuitry fixing stage to the support element 4.

The fixing stage of the blood treatment device to the support element 4 comprises the sub-stages of selecting a pair of connectors to which the counter-connectors 9, 10 on the blood treatment device are to be connected, applying a predetermined quantity of glue, normally polymer-resin based, in the annular seatings 21 of each chosen connector, at least partially inserting each counter-

connector in the respective annular seating in order to obtain a mechanical bond and a liquid-proof seal coupling.

During the insertion stage, at least a portion of the glue applied in the annular seating actually settles in the second zone 23 of the annular seating. On completion of the counter-connector insertion stage in the annular seating, the volume of the quantity of glue previously applied added to the volume of the portion of counter-connector housed in the annular seating is less than the overall volume of the annular seating. This prevents any glue material from migrating towards the tubular channel 16 and causing a partial or total occlusion.

The stage of associating a fluid distribution circuitry 15 to the support element 4 and the blood treatment device 5 comprises the sub-stages of liquid-proof sealing of an end portion of a discharge fluid discharge line 45 with the second end portion 14 of one of the connectors, and of sealedly fixing an end portion of a fresh dialysis liquid supply line 48 to the second end portion of a further of the connectors.

The stage of associating the blood distribution circuitry also includes sealedly fixing an end portion of a blood withdrawal branch 46 to an inlet port of the first chamber, and an end portion of a blood return branch 47 to an outlet port of the first chamber.

The fixing of the various above-mentioned end portions can be achieved by gluing, friction fitting or hot-coupling.

The invention provides important advantages.

Firstly, the direct fixing of the blood treatment device to the selected connectors of the support element does not require the use of other support elements of the same device.

Further, the connectors receive on one side the counter-connectors of the blood treatment device and on the other side the end portions of distribution circuitry lines, realizing a contemporaneous mechanical and hydraulic connection between the fluid distribution

circuitry and the blood treatment device.

The presence of various connectors means the treatment device can be used with connectors having different interaxes.

5 The special fixing modality of the blood treatment device and the various fluid lines to the support element considerably facilitates the assembly process of an integrated module according to the invention.

10 The specific structure of the integrated module and the support element minimises the length of fluid line needed to realize the connections with the blood treatment device.